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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/783,628

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Ricardo E. Paxson

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EXAMINER

ZHOU, SHUBO

ART UNIT

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1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/783,628	Applicant(s) PAXSON ET AL.	
	Examiner SHUBO (Joe) ZHOU	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/14/09 has been entered.

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are currently pending and under consideration.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is reiterated from the previous Office action with modified reasoning based on the recent court decision including *In re Bilski*, and in light of applicant's amendment filed 1/14/09.

The claims are drawn to a process, system or article of manufacture for modeling and simulation of a biological process comprising constructing a model of the biological process, generating and display dynamic behavior of the modeled biological process (as in claim 8, etc.) or analyzing the constructed model to generate a result and transmitting the result to the modeling component (as in claim 20, etc.).

The following analyses follow the rationales suggested in the Office's guidance to examiners under the Memorandum "Guidance for Examining Process Claims in View of In re Bilski" (signed January 7, 2009, available online at www.uspto.gov/web/patents/memorandum.htm) and the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, also available from the US PTO website at <http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>), which is incorporated in the MPEP 2106.IV.C.2.

Paragraph three of the Memorandum states:

"[A] method claim must meet a specialized, limited meaning to qualify as a patent-eligible process claim. As clarified in Bilski, the test for a method is whether the claimed method is (1) tied to a particular machine or apparatus, or (2) transforms a particular article to a different state or thing.

In the instant case, at least for this embodiment of the claimed invention, the claimed method is not tied to a particular apparatus or machine. Furthermore, there is no physical transformation because a process of mathematical modeling of biological process does not transform an article or physical subject to a different state or thing. It is noted that the claims, such as claim 8, recite "simulating the constructed model ... to transform the first set of data into

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a second set of data” This so-called transformation in the context of the claims, however, is not a physical transformation because it only transforms data to data, which is not physical, and does not transform an article or physical subject to a different state or thing.

Therefore, at least one embodiment of the claimed method is not a statutory process.

Note that the Office’s 1/7/09 Memorandum also points out based on the decision In re Bilski that “insignificant extra-solution activity will not transform an unpatentable principle into a patentable process. This means reciting a specific machine or a particular transformation of a specific article in an insignificant step, such a[s] data gathering or outputting, is not sufficient to pass the test.”

Additionally, the “Guidelines,” which is incorporated into the MPEP 2106.IV.C.2, states:

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.*
- The claimed invention otherwise produces a useful, concrete and tangible result.*

In the instant claims, there is no physical transformation for reasons set forth above.

Based on the Guidelines and the MPEP 2106.IV.C.2, for a claim to be “useful,” the claim must produce a final result that is specific, substantial, and credible. For a claim to be “tangible,” the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be “concrete,” the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again.

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Furthermore, the claim must be limited only to statutory embodiments. Thus, if a claim is broader than the statutory embodiments of the claim, the claim will be rejected as non-statutory.

The instant claims do not appear to produce a useful, concrete and tangible result. The claims, such as claim 8, construct a mathematical model, simulate the model to transform one set of data to another set that represents a second state of a plurality of chemical substances (such as step (b) of claim 8), and finally refine the model. Thus, the claims do not produce a tangible result because the final result is not used or made available to be used by a user. Therefore, the claimed invention does not produce a useful and concrete and tangible result.

Furthermore, claims 15-18, 40-43, and 77-81 are drawn to an article of manufacture comprising computer instructions. The claims read on a computer readable medium with computer instructions embodied thereon. While the instant specification does not explicitly define the scope of the limitation of “computer readable medium,” one skilled in the art would understand that computer readable medium includes carrier wave, which is a signal. For example, Fiekowsky et al., in US patent 6,090,555 (Date of Patent: July 18, 2000), define computer readable medium as being “a CD-ROM, floppy disk, tape, flash memory, system memory, hard drive, and a data signal embodied in a carrier wave.” See column 14, claim 12. Bornstein et al., in US patent 6,1443,88 (Date of patent : Nov. 7, 2000) state, “The computer readable medium of the present invention generally includes a tape, a floppy disk, a CD ROM, a carrier wave. In a preferred embodiment, however, the computer readable medium of the present invention is a carrier wave.” See column 8, lines 33-37.

Therefore, at least one embodiment of the claims is drawn to carrier wave or a signal encoded thereon a computer program.

It was held by the court that claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, per se, and as such, are nonstatutory natural phenomena. O'Reilly, 56 U.S. (15 How.) at 112-14. Moreover, it does not appear that a claim reciting a signal encoded with functional descriptive material, e.g. a computer program, falls within any of the categories of patentable subject matter set forth in § 101. See the US PTO's "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005).

With regard to claims 26-30 and 64-67, drawn to a system, because the method claims do not produce a useful, concrete and tangible result and are thus drawn to nonstatutory subject matter, the system claims for performing the process do not produce a useful, concrete and tangible result for the same reasons.

The rejection of the claims under 35 U.S.C. 101 for lacking patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility, and the related rejection of the claims under 35 USC 112, first paragraph, set forth in the previous Office action have been withdrawn in view of applicant's amendment to the claims filed 1/14/09.

Applicant's arguments filed on 1/14/09 have been fully considered but they are not persuasive. Applicant first argues that the claimed invention produce a useful result. This is moot because the current rejection is not made due to a lack of useful result in view of applicant's amendment. Applicant then argues that the court in *In re Bilski* noted that the transformation of

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data representative of an underlying physical object or substance was sufficient to confer patentability even without transformation of the underlying physical object or substance.

Applicant asserts that the instant claims are directed to transformation of data representative of chemical substances and thus directed to statutory subject matter. This is not found persuasive. In *In re Bilski*, the court made the above statement when reviewing previous court decision in *Abeles* where the court pointed out that the data is x-ray attenuation data produced in a two dimensional field by a computed tomography scanner, and thus represent physical and tangible objects. See 88 USPQ2d 1385, 1398 (Fed. Cir. 2008). In the instant case, however, the fact pattern is different and the data only represent a first state of a plurality of chemical substances (see step (a) of claim 8), which is different from the data in *Abeles* which is x-ray attenuation data produced in a two dimensional field by a computed tomography scanner. Furthermore, the instant claims recite that the model constructed by the instant claims only “include” a first set of data that represents the first state of chemical substances, not the physical chemical substances themselves. The data that represent a state of the chemical substances are not the data that are used to construct the model, simulate the model and refine the model, which appears to be the core of the claimed invention.

Claim Rejections-35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims, such as claims 8 and 20, are amended to recite the constructed model includes a first set of data representing a first state of a plurality of chemical substances and the first set of data is transformed to a second set representing a second state of the plurality of chemical substances in the modeled process. Applicant did not point out, and the Office was unable to find, adequate description in the disclosure of the instant application as support for the new limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al. (IDS document: WO 03/001891, 09 January 2003).

This rejection is reiterated from the previous Office action.

The claims are drawn to a method, system or article of manufacture for modeling and simulation of a biological process, the method comprising constructing a model of the biological process, generating and display dynamic behavior of the modeled biological process (as in claim 8, etc.) or analyzing the constructed model to generate a result and transmitting the result to the modeling component (as in claim 20, etc.).

Kelly et al. disclose a method and system for modeling and simulation of immune system including various biological processes. The method comprises providing data using graphical user interface and constructing a model of the immune system comprising components of immune responses using various mathematical equations including stochastic differential equations and Effect Diagram (see at least pages 9, 15), validating the model and using the model to produce simulated biological attributes associated with the biological state of the immune responses and compare simulated biological attributes with a corresponding biological attribute of a reference pattern of the immune response, which simulated biological attributes are interpreted as being dynamic behavior of the modeled process. See at least Fig. 3 and pages 21, 43-44. These are displayed in the various drawings disclosed by Kelly et al.

With regard to the new limitations that constructed model includes data representing a first state of chemical substances and the data are transformed to data representing a second state of the chemical substances, Kelly et al. disclose that the model includes data representing rate of change of biological variables such as metabolites, DNA, RNA proteins, etc., which are all chemical substances, and the data for rate of change represent a state of the chemical substances. The model also includes data such as equilibrium dissociation constant of IL-10, which is also data representing a state of the chemical. See at least page 9. Furthermore, the model includes data representing biological process, which is defined as interaction or a series of interactions between biological variables, which is defined as biological constituents making up the biological process such as metabolites, etc. See also page 9. The interaction is interpreted as a particular state of the chemical substances, i.e. the interacting state. Additionally, the model includes data representing biological state that includes disease state, which could refer to a

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disease protein such as a defective interferon-gamma receptor, which is a state of the chemical substance. See at least the paragraph bridging pages 11-12. Kelly et al. also disclose that the model can be simulated to produce simulated biological attributes based on parametric changes. See at least the paragraph bridging pages 21-22. This simulated attributes based on parametric changes are interpreted as a second state of the biological variables. Kelly et al. also disclose that a biological variable can be converted in the modeling process, and the first biological variable is converted into a converted biological variable the value of which changes over time. The series of simulated biological attributes produced represent the chronological progression of corresponding biological attributes. See page 22. This chronological progression is also interpreted to represent different state of the biological attributes. Thus data representing one state is transformed into data representing another state.

Kelly et al. do not explicitly teach modifying the constructed models by user commands received through both a graphical user interface and a textual interface.

However, Kelly et al. do state on page 11 that their “model can be modified to reflect The regions of interface can, for example, include” This indicates that their model can be identified and interface is used. Kelly et al. disclose that the computer system used for their modeling comprises a video display on which a user interface is displayed, which is interpreted as a graphical interface, and a network interface, which is interpreted as a textual interface. It would have been obvious to one having ordinary skill in the art that the purpose of having the user interface on a video display is to allow a user to use the interface on the video display to provide further convenience. Considering Kelly et al. disclose that their model can be executed by computer-executable software code representing dynamic biological processes including

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adaptive immune response (see page 8), it would be readily apparent to one skilled in the art that the model can be constructed or modified by receiving computer executable instructions received through the graphical and textual interfaces.

Furthermore, as the modeling, simulation and validation are also performed in computer systems with monitors and other display devices, all the results would be inherently displayed in the display devices involved. The Effect Diagram used in the modeling is considered a block diagram. Kelly et al. also disclosed the computer system and computer programs including codes for executing the method of modeling and simulations. See at least pages 41-42.

Therefore, one of ordinary skill in the art would have been motivated by Kelly et al. to modify their models as suggested by them in order to improve. Given Kelly et al. provide both graphical and textual interface, it would have been obvious that the commands from the user to modify the model would have been through either or both the graphical and the textual user interface.

Applicant's arguments filed 1/14/09 have been fully considered but they are not persuasive. Applicant again argues that Kelly et al. fails to teach or suggest that the constructed model is modified by user commands received through both a graphical user interface and a textual interface that is separate from the graphical user interface. See pages 14-15 of the response. This is not found persuasive because it would be readily apparent to one of ordinary skill in the art that an interface on a video display as disclosed by Kelly et al. would inherently be a graphical interface. For this, applicant argues that even though Kelly et al. disclose having the user interface on the video display, it does not teach that the user interface displayed on the video display is to be used to receive user commands. This is not found persuasive. As set forth above,

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it would be readily recognized by one having ordinary skill in the art that the purpose of a user interface is to allow a user to interact, i.e. receiving commands, etc, and the purpose to have the interface on the video display is to allow used to use the interface on the video display to receive commands, etc. so that it would be visual, a feature that would have been welcomed by a user for convenience and ease of use.

Applicant also argues that the network interface device disclosed by Kelly et al. is not used to receive user commands to modify a model but rather to receive software. See page 15. This is not found persuasive. As set forth in the previous Office action and reiterated above, Kelly et al. encourage modifying their model. It would have been obvious to one of ordinary skill in the art that in order to modify the model, commands would have to be transmitted and that an obvious route to transmit such commands would have been via the network interface device. Thus, it would have been obvious to one having ordinary skill in the art that the network interface would allow user interaction.

Applicant also argues that Kelly et al. do not teach or suggest automatically connecting elements of the model. See page 18. This is not found persuasive. Kelly et al. disclose various components of the model (interpreted as elements of the model as in the instant claims) on pages 25-31. Kelly et al. also disclose that this is computer implemented modeling process including disclosing computer codes for the modeling on Figs. 1, 3, 4, and 18, and pages 30, and 41-43. Given that the entire process is a computer implemented modeling process, it would have been apparent that the various components are also connected automatically via the computer process, such as in Figs. 1, 3, 4, 18, etc.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER